510(k) Summary

510(k) Number: K130467

Date of Original Submission: February 22nd, 2013

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
MedShape, Inc.
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318
Registration #10026693

DEC 0 5 2013

B. Company Contact:
Kenneth Dupont, Ph.D.
Technology Associate/Project Leader, Research & Development
(678) 235-3336 (direct)
(404) 249-9158 (fax)
kenneth.dupont@medshape.com

C. Device Information:
Trade Name: Porous *Morphix*® Suture Anchor with *Force Fiber*® Suture
Common Name: Suture Anchor

D. Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue
MBI 21 CFR 888.3040

E. Predicate Device(s):
MedShape, Inc., *WedgeLoc*™ Suture Anchor with *Opti-Fiber*™ Suture – now referred to as *Morphix*®, K091202

F. Labeling and Intended Use:
NOTE: Draft labels and instructions for use can be found in Attachment D.

The proposed *Porous Morphix*® Suture Anchor with *Force Fiber*® Suture has the same intended uses as our previously cleared predicate device in K091202. In particular, both devices are indicated for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow:	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

G. Substantial Equivalence Summary:

The proposed Porous *Morphix*® Suture Anchor with *Force Fiber*® Suture is a line extension to our *Morphix*® product family and is substantially equivalent to the *Morphix*® Suture Anchor with *Opti-Fiber*™ Suture, cleared under K091202, in which the features and intended uses are the same. In addition, the technological characteristics of the *Morphix*® and the Porous *Morphix*® Suture Anchor are equivalent. Analysis of non-clinical test results (monotonic and post cyclic suture fixation strength in Sawbone® bone analogue [pull-to-failure], dimensional verification, and material safety data [both bio and MRI compatibility]) supports the conclusion that the proposed device is substantially equivalent to the predicate device. Shear strength of the layer/implant body interface was also measured.

Differences between the Porous *Morphix*® Suture Anchor and the MedShape predicate *Morphix*® Suture Anchor include an extruded porous layer on the top surface of the device and a change in the preferred suture supplier (suture supplier CP Medical, previously cleared under K041894, was switched to suture supplier Teleflex Medical, previously cleared under K033654). This porous surface is derived directly from the implant body and is not a sintered coating. Based on the information submitted, MedShape, Inc. has determined that these differences do not raise questions concerning safety and effectiveness and that the proposed Porous *Morphix*® Suture Anchor is substantially equivalent to the currently marketed device.

12/04/2013

Kenneth Dupont, Ph.D.
Technology Associate/Project Leader, Research & Development

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

MedShape, Incorporated
Kenneth DuPont, Ph.D.
Technology Associate/Project Leader
1575 Northside Drive Northwest, Suite 440
Atlanta, Georgia 30318

December 5, 2013

Re: K130467
Trade/Device Name: Porous Morphix® Suture Anchor with Force Fiber Suture®
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 14, 2013
Received: October 15, 2013

Dear Dr. DuPont:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130467

Device Name: Porous *Morphix*® Suture Anchor with *Force Fiber*® Suture

Indications for Use:

The MedShape, Inc., Porous *Morphix*® Suture Anchor with *Force Fiber*® Suture is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder:	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow:	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices